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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,798	09/12/2003	Michel Samson	9409/2023F	8368

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,798	SAMSON ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) *1,6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1-5 and 11-15) pertaining to the polypeptide of SEQ ID NO:5 on 7/13/06, is acknowledged. Applicant's arguments have been found persuasive and Groups I and II are rejoined. All claims as they pertain to use of the polypeptide of SEQ ID NO: 5 wiil be examined. Claims directed to use of non-elected polypeptides of SEQ ID NOs: 4 and 6 must be amended (e.g. see claim 11).

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Europe on 3/1/96 and 8/6/96. It is noted, however, that applicant has not filed a certified copies of the EPO 96870021.1 and 96870102.9 applications as required by 35 U.S.C. 119(b).

Objections

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Although Applicant filed an Amendment on 12/15/03 to update the status of the related applications it is noted that the priority still needs amending. For example Application No. 09/938,703 is now patent 6,930,174. Appropriate correction is required.

4. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 16, Applicant has written "BRIEF DESCRIPTION OF THE FIGURES" . Further the description of the drawings is objected to because : Figure 1 should be described as Figures 1a-1e, Figure 2 as Figures 2a-2b, Figure 4 as Figures 4a-4b, Figure 6 as Figures 6a-6b, Figure 7 as Figures 7a-7b.

5. The significance of TABLE (KOA-3834.2) on page 35 is unclear. If this is a typographical error it should be removed to avoid confusion as to its significance.

6. Claims 1 and 6 are objected to due to the improper Markush grouping. The Markush group "comprising a sequence selected from the group consisting of SEQ ID NO:5" only has one group. A group cannot consist of one member. A group must be two or more members.

Drawings

7. The drawings were received on 2/17/04. These drawings are objected to by the examiner. Applicant has provided a replacement sheet for FIG. 6B. It appears Applicant is replacing Panel B of Figure 6 to include SEQ ID NOs. Original Figure 6b cannot be replaced by the new drawing because Original Figure 6 contained two panels, a and b. The new Figure 6 is labeled as Figure 6B. The question is where is Figure 6A. If the original Figure 6 is being replaced completely with the new Figure, and Applicant is wishing to remove Panel A, then the new drawing must be labeled as Figure 6. If Applicant is wishing to amend the drawing to include Panels a and b in separate sheets then new

drawings are required which should be labeled as Figure 6 A and 6B. The record is not clear as to applicant's intensions. Replacement FIG. 2, is also confusing. It is labeled as FIG. 2A, FIG2.B, FIG.2 and FIG.2A. It appears Applicant has replaced half of the original Figure 2 and called it 2A. The question is what figure is considered 2B.

Appropriate correction is required.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application for the reason given above. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

8. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states reference must be made to the sequence by use of the assigned identifier, the identifier being SEQ ID NO. Figure 6a contains a sequence but no SEQ ID NO:. Sequences in Figure 1 also require SEQ ID NO: identifiers. The amendment to Figure 1 reads" Figure 1A-1 and 1A-2 show the nucleic acid and amino acid sequence of SEQ ID NOs: 1 and 4, respectively. Figure 1B-I, 1B-2, and 1B-3 show the nucleic acid and amino acid sequence of SEQ ID NOs: 2 and 5, respectively. Figure 1D-1 to 1D-3 show the nucleic acid and amino acid

sequence of SEQ ID Nos. 3 and 6, respectively". Figure 1 does not contain Figure 1A-1,1A-2, 1B-I, 1B-2, 1B-3 and 1D-1 to 1D-3, it only contains FIGs. 1a-e, where FIGs 1a and 1e do not have legible SEQ ID NO: identifiers.

All sequences in the Figures and specification must be in sequence compliance and be identified by their corresponding SEQ ID NO:.

Appropriate correction is required***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, 10 and 15 are rejected as indefinite because based on the specification (page 5) the metes and bounds of "a portion thereof" (referring to portions of glycoprotein GP120/GP160) are not clear. The specification discloses, "It is meant by a "portion of the glycopeptide gp120/160" any epitope, preferably an immuno-dominant epitope, of said glycopeptide which may interact specifically with the peptide according to the invention, such as for instance the V3 loop (third hypervariable domain)." The claims are rejected as indefinite because based on the specification it is not clear which "portion thereof" (referring to portions of glycoprotein GP120/GP160) would "interact specifically with the peptide according to the invention". It is not clear what would be considered the "peptide according to the invention" and what portion of glycoprotein GP120/GP160 would interact specificity with said peptide. Further

the term "interact specifically" is not defined so as to allow the metes and bounds of the claims to be determined. Specificity is measured in terms of Km or Kd. The specification does not define "specifically" in terms of Km and Kd.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-9 and 11-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 –11 of U.S. Patent No. 6,800,447. Although the conflicting claims are not identical, they are not patentably distinct from each other because they disclose the same method steps which identify a compound that binds to the polypeptide of SEQ ID NO:5 and decrease infectivity of a cell by HIV.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 5, 10 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method according to claims 3, 8 or 13 wherein said HIV protein is glycoprotein GP120/GP160, does not reasonably provide enablement for use of undefined portions thereof as indicators of infectivity of the cell by HIV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

For the claimed method to achieve the goal of the preamble the infectivity of the cell to HIV infection must be identified. Measuring the glycoprotein GP120/GP160 achieves this goal. Measuring a defined portion of GP120/GP160 such as the V3 loop (see page 5) also achieves this goal. The critical structural feature which defines the glycoprotein GP120/GP160 is not disclosed in the specification. A portion of the glycoprotein GP120/GP160 which contains the critical feature of GP120/GP160, the critical feature which defines said glycoprotein, and which when measured would unambiguously identify the HIV infection is not disclosed or defined with enough clarity so as to allow the invention to be practiced in its full scope as claimed. The specification does not provide a clear definition of which portions of GP120/GP160 could be used in the assay to clearly determine HIV infectivity. As disclosed above the specification

discloses, "It is meant by a "portion of the glycopeptide gp120/160" any epitope, preferably an immuno-dominant epitope, of said glycopeptide which may interact specifically with the peptide according to the invention, such as for instance the V3 loop (third hypervariable domain)." There is no disclosure which "portion thereof" (referring to portions of glycoprotein GP120/GP160) would "interact specifically with the peptide according to the invention". What epitopes are immuno-dominant? What would be considered the "peptide according to the invention" and what portion glycoprotein GP120/GP160 would interact specificity with said peptide? Further the term "interact specifically" is not defined. Specificity is measured in terms of Km or Kd, the association or dissociation constants associated with "a portion thereof" are not disclosed.

The amount of experimentation required to make and/or use the "portions thereof" in their full scope would require trial and error experimentation to determine which glycoprotein portions would function in the assay as desired, i.e. to measure infectivity. Given the breadth of claims, the lack of working examples, the level of skill of the artisan, and the lack of guidance as to the critical structural feature which defines the glycoprotein GP120/GP160, or the smallest portion of glycoprotein GP120/GP160 that could be used to practice the invention undue experimentation for one of skill in the art to make and use the claimed invention, in its full scope.

12. No claim is llowed

Advisory

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nirmal S. Basi
Art Unit 1646
10/16/06

Eileen B. O'Hara
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PRIMARY EXAMINER